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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,940	05/02/2001	Michael J. May	PPI-117CP	6156
959	7590	12/05/2003	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			MITRA, RITA	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 12/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/847,940		MAY ET AL.	
	Examiner		Art Unit	
	Rita Mitra		1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 14-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 27-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

Applicants' election without traverse of Group I (claims 1-13 and 27-34) and SEQ ID NO: 6 (filed on August 25, 2003) is acknowledged. Claims 14-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention. Therefore, claims 1-13 and 27-34 are currently pending and are under examination. It should be noted that restriction required in office action dated July 23, 2003 didn't require a species election. It required election of one peptide defined by sequence.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-4, 6-13, 27-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 10, 11, 27, 31, 32 and 34 are indefinite because of the use of the term "NEMO". An acronym/abbreviation should be preceded by the full spelled out word. Claims 4 and 13 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

Claims 2, 3, 11, 12, 27 and 31 are indefinite because of the use of the term "IKK." An acronym/abbreviation should be preceded by the full spelled out word.

Claims 2, 7, 8, 9, 11 and 31 are indefinite because of the use of the term "capable." It is not clear whether the anti-inflammatory compound actually blocks... (claim 2, 11, 31) and capable of inhibiting... (claim 7, 9) and capable of down-regulating... (claim 8), or merely have the capability to do so. The word capable associates with the latent function only.

Claim 6 and 27 indefinite because they lack essential steps as claimed in the method of treatment of inflammatory disorder or treating an NFkB-mediated condition in a subject. The omitted steps are: the site and method of administration, and a step whereby the desired outcome and the time for the effective treatment using anti-inflammatory compound can be determined. Claims 7-9 and 28-34 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 27, 32 and 34 are rejected under 35 U.S.C. 102(b) as anticipated by Houston et al. (US 5,166,133, November 24, 1992). Houston et al. teach a method for inhibiting adhesion of white blood cells to endothelial cells to prevent inflammatory type diseases by administering proteins selected from inter-alpha-trypsin inhibitor, alpha1-M and HI-30 (see abstract, summary of the invention, SEQ ID NO: 17, col 27), wherein the peptide derived from alpha1-M has 100% sequence identity to SEQ ID NO: 6 (see sequence alignment result, Issued_Patents_AA database, Accession NO: US-07-700-526-17, August 16, 1991). Houston's peptide is considered identical to the anti-inflammatory compound of methods claims 1,5 and 27, 32 and 34 of instant application. Since Houston's protein is considered identical to anti-inflammatory compound of methods claims 1,5 and 27, 32 and 34, therefore the sequence of this protein is considered to have the NEMO binding domain of the claimed anti-inflammatory compound, and also contacting a cell with an effective amount of this sequence would have benn modulated the NF-kB induction in that cell. Thus anticipating claims 1, 5, 27, 32 and 34.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rita Mitra, Ph.D.
November 29, 2003


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